REMARKS

Prior to the foregoing amendment, claims 2-4, 6-7, 10-12, 14-21, 38, 40, 45, 51-56, 60, 61 and 63-83 were pending in the application, with claims 41, 43, 82 and 83 having been withdrawn from consideration as being drawn to a non-elected species as a result of an earlier election requirement. Pursuant to the February 13, 2006 Office Action, all pending claims stand rejected.

By the foregoing amendments Applicants have amended claims 2, 3, 6, 7, 14, 15, 18, 38, 41, 43, 51-54, 56, 63, 64, 66, 67, 73, and 75-80; cancelled claims 4, 55, 65, and 74; and introduced new claims 84-85. Applicants respectfully request reconsideration in light of the amendments and the following discussion.

Claim Amendments

As noted, Applicants have now amended claims 2, 3, 6, 7, 14, 15, 18, 38, 41, 43, 51-54, 56, 63, 64, 66, 67, 73, and 75-80 and added new claims 84 and 85. No new matter has been entered by any of the amendments or the new claims. Specifically,...

- Each of the independent claims, claims 38, 63, 64 and 73, has been amended to incorporate the claim limitation that the antimicrobial agent is an "ion-exchange type antimicrobial agent comprising a ceramic carrier and ion-exchanged antimicrobial metal ions" so as to expedite examination and allowance of the preferred and commercial embodiments of the present invention in light of competitive concerns. No inference should be drawn as to the validity of or Applicants' concession to the rejections relative to the broader claim scope and Applicants hereby reserve the right to file a further continuation application to the broader claims as previously presented. Applicants have concurrently canceled dependent claims 55, 4, 65, and 74, respectively, as they are now moot in light of the foregoing amendment.

- Each of the independent claims, claims 38, 63, 64 and 73, has also been amended to specify that the extent of water absorption of the hydrophilic polymer must be "sufficient to allow for ion transport within and through the hydrophilic polymer so as to facilitate the ion-exchange and subsequent release of an antimicrobially effective amount of the antimicrobial metal ions." This language makes clear that ion transport is critical to the compositions of the present invention. Support for this language is inherent from the specification as a whole, especially Paragraphs 27, 28 and 33.

- Independent claims 38 and 63 have been further amended to specify both a lower and a revised upper limit for the average particle size of the antimicrobial hydrophilic polymer microparticles. In following dependent claims 51-54 have been revised to restate the preferred upper and lower limits for the average particle sizes. These revised limits are fully supported in the specification at Paragraph 57.

- Independent claims 38 and 63 and dependent claims 14, 15 and 43 have been amended to delete the reference to "microcapsule" and instead refer to the additive particle as a microparticle. This amendment is for clarification purposes so as not to infer that the antimicrobial additives of these independent claims are core-shell type capsules. As is clear from the specification and the claim language itself, the claimed additives are hydrophilic polymer microparticles having dispersed therein particles of a solid ion-exchange type antimicrobial agent. These particles of the antimicrobial agent will be at the surface as well as within the body of the hydrophilic polymer microparticle.

- Independent claims 64 and 73 have been further amended to correct the wording of the upper limit for the average particle size, thereby rendering it consistent with independent claims 38 and 63 and the specification overall. This amendment is fully supported by Paragraph 57.

- Dependent claims 2, 3, 66, 67, 76, and 77 have been amended to remove the reference to "metal or" solely for the purpose of ensuring proper antecedence since the claims now only require that the ceramic carrier have antimicrobial metal ions. This is not, however, to infer that the ceramic carriers must be free of any and all metal. Indeed, some metal may be present so long as the antimicrobial agents are antimicrobially effective in the absence of the same.

Finally, the remaining amendments concern revising claim dependency and/or editorial corrections for simplicity of understanding in light of other claim amendments. Again, no new matter has been entered and it is firmly believed that the claims as now presented are in proper form for allowance.

Claim Rejections

Rejection under 35 USC §112, Second Paragraph

Claims 2-4, 6, 7, 10-12, 14-21, 38, 40, 42, 45, 51-56, 60, 61, 63-68, 70-77 and 79-81 stand rejected under 35 USC §112, second paragraph, as failing to set forth the subject matter whish applicant(s) regard as their invention. In raising this rejection, the Examiner points to the

prior response in which Applicants' arguments endeavored to distinguish the claimed invention over the cited art on the basis of specific, preferred embodiments which were not the focus of the rejected claims.

By the foregoing amendments, Applicants have now narrowed the scope of the claims to those embodiments wherein the antimicrobial agent is an ion-exchange type antimicrobial agent comprising a ceramic carrier and ion-exchanged antimicrobial metal ions having, relative to independent claims 38 and 63, an average particle size of from about 15μ to about 300μ, and relative to independent claims 64 and 73, an inherent minimum average particle size of (2μ+x) where x is the average diameter/particle size of the ion-exchange type antimicrobial agent and a maximum particle size of 300μ. The claims are now consistent with the prior arguments and the preferred and commercial aspect of the invention. In light of the foregoing amendments, it is believed that this rejection is now rendered moot and should be withdrawn.

Rejection under 35 USC §112, First Paragraph

Claims 74-80 are rejected under 35 USC §112, first paragraph, as being indefinite for failing point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner points out that each of these dependent claims recites an "antimicrobial additive" according to claim 73 when in fact claim 73 is directed to a polymer composition.

Applicants have amended the claims to make the proper characterization. In light of the foregoing amendments, the rejection is believed to be moot and, therefore, the rejection should be withdrawn.

Rejection under 35 USC §102(b) or 103(a) over JP 11-222402 ("Osaka")

Claims 2-4, 10, 11, 14, 15, 38, 42, 55, and 63 stand rejected under 35 USC §102(b) as being anticipated by, or in the alternative, under 35 USC §103(a) as being obvious over Osaka (JP 11-222402). Osaka is cited as teaching "antimicrobial acrylamide particles (mean particle diameter of 60-90 nm, 90-120 nm and 90-120 nm) containing silver (22.8% by wt., 35.2% by wt. and 25.7% by wt.) which are incorporated into Aronix UV-3701 or ARON NS-1200 and hardened to form a film falling with the scope of applicant's claims." In the alternative, the Examiner alleges that, "at the very least, the claimed invention is rendered obvious...because the

prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention."

Applicants respectfully traverse the rejections and request reconsideration in light of the foregoing amendments. Specifically, the claims, as currently amended, are directed to antimicrobial hydrophilic polymer microparticles and polymer compositions incorporating the same wherein the antimicrobial agent is an "ion-exchange type antimicrobial agent comprising a ceramic carrier and ion-exchanged antimicrobial metal ions" and wherein the microparticles have a minimum average particle size of about 15μ and a maximum average particle size of about 300μ. These materials, and the products produced therewith, are quite distinct from the ingredients/components of Osaka. Furthermore, Osaka specifically teaches away from the use of such ion-exchange type materials: describing the problems associated therewith and endeavoring to avoid them (See Paragraph 003) as well as employing one, a silver zeolite, as a comparative material. Thus, Osaka neither anticipates nor renders obvious the claimed antimicrobial additives or the antimicrobial compositions incorporating the same and, therefore, Applicants respectfully request that the rejection be withdrawn and claims 2-4, 10, 11, 14, 15, 38, 42, 55, and 63 be passed on to allowance.

Rejection under 35 USC §103(a) over Osaka in view of JP 4-66512 ("Shintokogio") and Turner et. al. (US 2003/0043341)

Claims 2-4, 10-12, 14-17, 19-21, 38, 40, 42, 45, 51-55, and 63 stand rejected under 35 USC §103(a) as being unpatentable over Osaka in view of Shintokogio and Turner et. al. Osaka is cited for the teachings set forth above as well as for teaching that the hydrophilic polymer particles a) contain an antimicrobial metal such as silver, platinum, copper, zinc, etc., b) can have a diameter of 0.1 nanometers to 100 micrometers, and c) can be incorporated into a resin including polyethylene, polypropylene, ABS, epoxy resin, styrene resin, and polyvinylchloride; wherein the hydrophilic polymer d) can be composed of hydroxyl content monomers such as alkyl(meth)acrylate, nitrogen content monomers such as vinyl-pyrrolidone and acrylamide, and polyisocyanate, e) can contain two or more different hydrophilic units and f) is compatible with hydrophobic resin and wherein the antimicrobial metal can be in the form of a complex with a quarternary ammonium compound which also has antibacterial activity. Shintokogio is cited as teaching an antimicrobial silver salt coated with polyurethane resin prepared from

polyisocyanate and incorporating the same in thermoplastic and thermoset resins. Turner et. al. is cited as disclosing sodium nitrate reducing discoloration caused by silver.

The Examiner states that the difference between the art and the claimed invention is that the art does not expressly disclose an inorganic antimicrobial which is encapsulated with hydrophilic polymer having an average diameter of about 2000 microns or less, further comprising at least one of the following: an ammonium salt, sodium nitrate, incorporation into an addition polymer, an average diameter of from about 15 to 1000 microns or about 50 to 300 microns. However, the Examiner contends that the art amply suggests the same as the art discloses i) hydrophilic particles of overlapping sizes containing inorganic antibacterial agents and the incorporation thereof in addition polymers, ii) the coating of antibacterial silver salt with polyurethane and the incorporation thereof into resin, and iii) the use of ammonium ions and sodium nitrate. It is alleged that it would have been well within the ability of one of ordinary skill in the art and one of ordinary skill would have been motivated to modify the prior art as above with the expectation that the combination of antibacterial inorganic salts and hydrophilic polymers would result in increased antibacterial activity, that the addition of ammonium ions would provide greater antibacterial activity and the sodium nitrate would inhibit discoloration of the polymer composition.

The Examiner states that Applicants' arguments have been considered but are not persuasive for the foregoing reasons, particularly in light of Osaka specifically disclosing particle sizes that overlap with the claimed particle sizes. It is further stated that the submitted Trogolo article is insufficient to overcome the rejection inasmuch as the claims do not set forth a minimum size of the inorganic antimicrobial agent and, furthermore, it is not unexpected that the larger micron sized particles would have more silver than the nano sized particles. It is stated that the claimed invention as a whole is prima facie obvious because every element of the invention has been collectively taught by the combined teachings of the references.

Applicants respectfully traverse the rejection and request reconsideration in light of the foregoing amendments and the following discussion. Contrary to the Examiner's assertion, there is no scientific basis for the conclusion or presumption that a metal atom that is chemically bonded to and thereby forms a part of a polymer chain or cross-linked polymer network is equivalent to or the same as a discrete particle of an inorganic antimicrobial agent dispersed in a

hydrophilic polymer. Regardless, as amended, the claims specifically require an ion-exchange type antimicrobial agent comprising a carrier and ion-exchanged antimicrobial metal ions, which clearly distinguishes over Osaka. Furthermore, Osaka makes no suggestion or motivation to encapsulate or disperse an inorganic antimicrobial agent in a hydrophilic polymer wherein the so formed antimicrobial hydrophilic polymer is in the form of microparticles having a minimum average particle size of about 15μ and a maximum average particle size of about 300μ. Despite the apparent overlap between the presently claimed particle size and the broad disclosure of Osaka, Osaka is clearly directed towards particle sizes that are generally two to three orders of magnitude smaller. Indeed, the upper end of Osaka's disclosed range, above 1μ, certainly above 5μ, appears to be in direct conflict with one of the very objectives of Osaka, i.e., the avoidance of large particle size antimicrobial agents such as Applicants' silver zeolites (See Paragraph 003). In any event, as discussed above, Osaka specifically teaches away from inorganic antimicrobial agents and, in particular, ion-exchange type antimicrobial agents like silver zeolites. Thus, there is no motivation to combine the teachings of Shintokogio, which employs silver zeolites, silver salts, etc., with Osaka. Furthermore, based on Osaka's teachings in view of the Examiner's conclusion that such a combination would produce enhanced antimicrobial activity, one would expect that the combination would only exacerbate the problems Osaka has identified as being associated with inorganic, especially ion-exchange type, antimicrobial agents (i.e., discoloration, settling, erosion, etc.): the very problems Osaka is trying to avoid and address.

Reliance upon Shintokogio does not help overcome the shortcoming of Osaka. Shintokogio coat silver zeolites with a non-hydrophilic polyurethane: that the polyurethane is non-hydrophilic is self-evident from Shintokogio's characterization that the polyurethanes are non-hygroscopic and from Table 1 and the related discussion wherein the polyurethane manifested no water absorption as well as, perhaps most importantly, from the very objective of Shintokogio, i.e., altering the inherently hydrophilic surface characteristics of the zeolite to make it more compatible with a hydrophobic matrix resin. Certainly, one would not employ a hydrophilic coating if the objective is to change the hydrophilic nature of the particle being coated. As set forth in In Re Hedges (783 F2d 1038, 228 USPQ 685 (fed Cir. 1986)), "... the

totality of the art must be considered and proceeding contrary to accepted wisdom is the art is evidence of non-obviousness."

In light of the foregoing, nothing in Osaka or Shintokogio suggests, motivates or infers the preparation of antimicrobial additives comprising a hydrophilic polymer and an ion-exchange type antimicrobial agent. Thus, the rejection based on the combined teachings of these references fails and should be withdrawn.

Further reliance upon Turner et. al., either as evidence of encapsulated antimicrobial agents or the use of sodium nitrate as a dopant, does nothing to support the rejection. Turner et. al. teach the coating of antimicrobial silver zeolite with a **hydrophobic** material: the very opposite of the present invention. Though Turner et. al. do mention the use of sodium nitrate, they do so as an oxidizing agent to be used when the antimicrobial agent is silver metal (See Paragraph 62). As taught by Turner et. al., the oxidizing agent removes an electron from the silver atom to produce silver cations (Ag^{+1} and Ag^{+2}): the clear inference being that silver in the ionic state does not manifest the same discoloration issues as silver metal. Since the silver component in Applicants' claimed compositions is already in the cationic state, there is no need or motivation for the use of an oxidizing agent.

Finally, the Examiner's dismissal of the Trogolo article on the basis that it is not unexpected and readily apparent that 100 micron sized particles can hold more silver than nano-sized particles evidences a lack of appreciation of the true teaching and significance of the Trogolo article. As shown in Figure 5 of the Trogolo article, four compositions were prepared, **each having the same loading (wt%) of the specified antimicrobial agent in polyethylene;** yet, the samples containing the smaller particle sized antimicrobial agents, even though they and the resultant polymer composition have considerably higher silver contents, had markedly reduced silver reservoirs, i.e., silver available to provide antimicrobial activity. As discussed in specification and Applicants' prior responses, antimicrobial efficacy and longevity in hydrophobic compositions depends not on the total silver content of the composition but on how much silver available. Availability depends upon that which is present at or in immediate proximity to the exposed polymer surface. Using the formula on Page 2 of the Trogolo article, Osaka would have to use 35 times the amount of its 100nm, 35.2% silver content, antimicrobial agent, i.e., 35% by weight, in order to provide the same amount of available silver ions as

present in a polymer composition containing only 1% by weight of a 100 micron particle size encapsulated silver zeolite having only 1.25% silver content. This is not a matter of degree but an entirely different system.

In light of the foregoing discussion and the amendments to the claims, it is believed that the claims as now presented clearly distinguish over and are patentable over the art of record. Nothing in the cited references teach or suggest microparticles of a hydrophilic polymer having dispersed therein an ion-exchange type antimicrobial agent, especially wherein the microparticles of are of a narrowly defined average particle size range, or the use thereof as an antimicrobial additive for polymer coatings or compositions with the expectation of improved antimicrobial performance and longevity. Thus, Applicants respectfully request that the rejection of claims 2-4, 10-12, 14-17, 19-21, 38, 40, 42, 45, 51-55, and 63 over Osaka in view of Shintokogio and Turner et. al. be withdrawn and the claims passed on to allowance.

Rejection under 35 USC §103(a) over Shintokogio in view of Takebayashi et. al. (US 6,113,936), Niira et. al. (US 5,556,699), Wada et. al. (US 3,981,970) and Turner et. al.

Claims 2-4, 6, 7, 10-12, 14-21, 38-40, 42, 44, 45, 51-56, 60, 61, and 63-83 stand rejected under 35 USC §103(a) as being unpatentable over Shintokogio in view of Takebayashi et. al., Niira et al., Wada et. al., and Turner et. al. for the reasons of record and the following:

- Shintokogio is cited as teaching polyurethane coated silver zeolites and the incorporation thereof in thermoplastic and thermoset resins for providing antimicrobial activity. The silver zeolites are said to be prepared by the addition of silver nitrate and ammonia and the so formed materials are coated with from 1.5% to 3% by weight of the polyurethane resin.

- Takebayashi et. al. teach a method of microencapsulating silver zeolite with polyurethane where the average diameter of the obtained microcapsule is usually from 0.1 to 300μ, preferably from 0.5 to 200μ and the core particle is usually from 0.1 to 200μ, preferably from 0.5 to 100μ.

- Niira et. al. is cited as teaching antibiotic silver zeolites further incorporating ammonium ions for the prevention of discoloration of resins into which they are incorporated.

- Wada et al. is cited as teaching the equilibrium reaction for cation-exchange in zeolites, including the exchange process where silver ions are introduced to sodium containing zeolite whereby silver zeolites and excess silver ions and sodium ions result, as well as an exchange

process where nitric acid is introduced to silver zeolite with the result being hydrogen zeolite, silver nitrate and excess nitric acid.

- Turner et. al. is cited as teaching that sodium nitrate reduces discoloration caused by silver.

In making its rejection, the Examiner acknowledges that the prior art does not expressly disclose an inorganic antimicrobial which is encapsulated with hydrophilic polymer having an average diameter or 2000 microns or less, optionally further comprising an ammonium salt or sodium nitrate or optionally further incorporated into an addition polymer. However, the Examiner alleges that the prior art amply suggests the same as antibacterial silver zeolites to be incorporated into addition polymers; the combination of antibacterial silver zeolites and hydrophilic polymers, such as polyurethane; and the use of ammonium ions and the exchange of silver with sodium ions and nitric acid. The Patent Office further alleges that it would be well within the skill of one of ordinary skill in the art to modify the prior art as Applicants have with the expectation that the combination of antibacterial silver zeolites and hydrophilic polymer would result in increased antimicrobial activity, that the addition of ammonium ions would inhibit discoloration of polymer resin in which the silver zeolite is incorporated and that the addition of a salt of sodium ion and nitric acid, i.e., sodium nitrate, would drive the silver ions out of the zeolite, thereby increasing the amount of free silver ions available for antibacterial effect.

The Examiner states that Applicants' prior arguments have been considered but are not deemed persuasive for the same reasons elucidated above and as follows. Specifically, the Examiner states that reliance upon embodied examples and preferred embodiments and/or alternatives as a teaching away from the broader scope of the cited art are neither persuasive nor sufficient to overcome the rejections. Additionally, the Examiner asserts that the art may provide the motivation to produce the claimed invention even though it does it for an entirely different reason or purpose. Finally, the Examiner states that the mere presence of a non-ionic surfactant is not suitable evidence that the encapsulated materials of Takebayashi et. al. do not contemplate the incorporation of multiple particles of the solid substance.

Applicants respectfully traverse the rejection and request reconsideration in light of their prior arguments, which are hereby reiterated and incorporated herein by reference, and the

arguments below. As previously discussed, *prima facie* obviousness is not founded on the mere presence of each element of the claimed invention in a plurality of references. Rather, the Patent Office must look at the whole of the teachings of the prior art as well as the distinctions between the prior art and the presently claimed invention. Looking at the whole of the teachings of the prior includes, by necessity, looking at all that is taught, not merely that which supports the Patent Office's arguments. Furthermore, the Patent Office must also provide proofs that the cited references teach, suggest or motivate the combination of the specific prior art references in such a way as to arrive at the particular combination with its attendant properties/performance as claimed by Applicants. The Patent Office has failed in these respects.

The Examiner's inference that Shintokogio and Takebayashi et. al. teach the encapsulation of silver zeolite with a hydrophilic polyurethane is unfounded. Nothing in either reference identifies, suggests, or infers that the polyurethanes are hydrophilic or that hydrophilic polyurethane is even an option. Further, as discussed above, Shintokogio clearly specifies that its polyurethane is not hydrophilic. While Takebayashi et. al. is silent on the distinction, the teaching of the art cited by the Examiner as a whole is clearly towards hydrophobic coatings. Indeed, Turner expressly teaches encapsulating silver zeolites in hydrophobic polymers. It is well established that a line of development flowing from the cited references will teach away if it is unlikely to be productive of the results sought by the patent applicant. (See In Re Gurley, 27 F3d 551, 553 (Fed Cir 1994))

Generally speaking, none of the cited art suggests, infers or motivates one to encapsulate an ion-exchange type antimicrobial agent in a hydrophilic polymer. Rather, the motivation in the art is to do the opposite and encapsulate with a non-hydrophilic polymer in order to avoid the many problems associated with the incorporation of the inherently hydrophilic zeolites in a hydrophobic polymer. While the Examiner's comment relative to Turner that "it would be obvious to avoid using the hydrophobic coatings if slow release of the silver was not desired" may have merit, one is merely left with an uncoated zeolite. It still does not suggest or motivate one to use a hydrophilic coating or to obtain the unexpected benefits with the same as found by Applicants. Thus, contrary to the assertion of the Examiner, no finding of prima facie obviousness has been established or, in the alternative, it has been fully rebutted.

Further, though the Examiner suggests that the mere inclusion of an anionic surfactant does not infer that Takebayashi et. al. is limited to individually encapsulated zeolites, Applicants believe the specification of Takebayashi et. al. as a whole amply supports such a limitation. At the very outset, Takebayashi et. al. explains that one of its key objectives is to avoid the agglomeration of core particles typically found when endeavoring to encapsulate inorganic core particles (See col. 1, lines 25-46). And, throughout the specification, Takebayashi et. al. speak of the importance and desire of creating a dispersion, especially a uniform or homogeneous dispersion, of the core particles (See Col. 3, line 63 thru Col. 4, line 52, especially Col. 4, lines 43-47). Furthermore, the concept of a core particle and of the coating covering the core particle (Col. 4, lines 48-52) inherently infers a core-shell configuration: a polymer particle having dispersed therein multiple particles of a solid substance would not have a core per se. Finally, when speaking of the particle size, Takebayashi et. al. repeatedly mention that particle size is largely dependent upon the core particle and teaches that when the core particles are too large, they are to be further crushed or, if too small, they are to be recrystalized or granulated and then crushed to the desired size. Obviously, if a single microcapsule employed multiple particles of the core material, one would not have such a concern with the particle size of the core particle, especially with respect to the core particles being too small. Thus, Applicants' believe that Takebayashi et. al. is most certainly directed to the coating of individual particles.

Further, while the cited references teach coating individual particles, they do not suggest the use of a hydrophilic material as the encapsulating or coating material nor do they teach a coating thickness on the order of 1μ to 15μ, as required by independent claims 64 and 73. Instead, as discussed above and in the prior response, they, as a matter of necessity, employ coatings of a thickness that are but a fraction of the presently claimed coating thickness. (See footnote (a) in Applicants' prior response) Hydrophobic coatings of the presently claimed thickness would cause the loss of antimicrobial efficacy (or more appropriately the failure of antimicrobial activity to manifest) due to the inherent loss pathways for the transport of the antimicrobial metal ions. Specifically, as the thickness of the hydrophobic polymer coating increases whatever pores may exist in the monolayer are covered or closed off by successive layers of the polymer material.

In light of the foregoing discussion, it is clear that neither Shintokogio nor Takebayashi et. al., alone or in combination with each other or in further combination with Turner et. al., teach, motivate or suggest the preparation of individually encapsulated ion-exchange type antimicrobial agents wherein the encapsulating material is a hydrophilic polymer whose water content is at least 5 weight percent and is present at a coating thickness of between 1 micron and 15 microns, let alone the desirability and benefits of doing so for increasing the effective particle size and enhancing the effectiveness and longevity of an ion-exchange type antimicrobial agent, when incorporated into a polymer material, either as a molding composition, coating or the like. Furthermore, neither reference teaches, suggests or motivates one to encapsulate a plurality of particles of an ion-exchange type antimicrobial agent into a single microcapsule for the purpose of increasing the effective particle size as well as markedly enhancing the antimicrobial efficacy and longevity thereof by creating large reservoirs of antimicrobial active. Thus, the Patent Office has not proven or established prima facie obviousness of the present.

While the Examiner is correct in that the art has recognized the ability of ammonium ions to inhibition of discoloration, the art has not recognized the improved antimicrobial properties and concurrent lessened discoloration (even with the same level of ammonium ions) resulting from the incorporation of ammonium charged silver zeolite in a hydrophilic polymer particle. It is well recognized in the art that discoloration largely arises from chemical interactions that occur during processing/incorporation of the antimicrobial agent into a polymer matrix (see for example the paragraph bridging pages 5 and 6 of Shintokogio): though the actual discoloration may not manifest itself until exposed to certain conditions, for example, UV light. In the present invention, such interaction is limited to the polymer microparticle incorporating the antimicrobial agent: not the polymer matrix into which the microparticle is subsequently incorporated in use. Thus, following UV exposure, a film of a water-clear polymer made with the antimicrobial additives of the present invention, upon close examination, will essentially reveal microdots of discolored polymer corresponding to the antimicrobial microparticles dispersed in a clear film matrix; whereas, a similar film prepared with an equivalent loading of a non-encapsulated antimicrobial will manifest uniform discoloration across the matrix polymer of the film. Visually, the latter will be markedly less transparent or more discolored than the former. Thus, while the presence of the ammonium ions helps reduce discoloration,

encapsulation of the antimicrobial agent with a hydrophilic polymer also has a marked effect on the manifestation of discoloration.

Finally, the Examiner's suggestion that the use of sodium nitrate as dopant is logical in light of the action of sodium and nitric acid as disclosed in Wada is unfounded. Certainly there is no logical reasoning by which this conclusion can be reached: if there is, the Examiner should spell it out. Further reliance upon Turner et. al. does not help for, as discussed earlier, Turner et. al. teaches sodium nitrate as an oxidizing agent for silver metal. Nothing in Wada et. al. and/or Turner et. al. suggests the use of sodium nitrate with an ion-exchange type antimicrobial agent having antimicrobial metal ions on a ceramic carrier. Regardless, even if there were some inference in either Wada et. al. or Turner et. al. that sodium nitrate could act as a dopant to enhance the release of silver ions from a silver zeolite, the teachings of the cited art would, as a whole, teach against this use. As noted above, the majority of chemical species or constituents responsible for the manifestation of discoloration in polymer compositions are created during the processing/incorporation of the antimicrobial into the polymer matrix. Employing an agent to enhance the release of silver ions would merely result in increased discoloration: an adverse consequence that the cited art and many others have and continue to seek to overcome. Clearly, this would be contrary to the accepted wisdom of the art and, thus, evidence patentability of Applicants' invention (See In Re Hedges, 783F2d 1038, 228 USPQ 685 (Fed Cir 1986)).

Furthermore, since Applicants' encapsulated antimicrobial additives allow for the use of less antimicrobial active to affect the same level of antimicrobial activity as a non-encapsulated antimicrobial agent and essentially limit discoloration to the polymer matrix of the microparticle, polymer compositions incorporating the same will manifest markedly less discoloration even with the dopant. Thus, inasmuch as the art fails to make obvious the antimicrobial hydrophilic polymer particles, as claimed, and fails to recognize the unexpected benefits without the anticipated problems of the further use of sodium nitrate as a dopant, there has been no showing of prima facie obviousness or, in the alternative, such showing has been fully rebutted.

For all the reasons set forth above, it is clear that the Patent Office has not proven or demonstrated prima facie obviousness. None of the references alone or together teach or even suggest Applicants specific antimicrobial additives or antimicrobial compositions containing

such additives. None of them teach or suggest the ability to increase the antimicrobial efficacy of a composition by increasing its effective particle size. None of them teach or suggest the benefits of enhanced antimicrobial activity as a result of creating reservoirs of antimicrobial active in hydrophilic polymer particles. And, none teach or suggest the other benefits of the additives of the present invention and their use as discussed above and in the specification. Consequently, the rejection based on Shintokogio in view of Takebayashi et. al., Niira et. al., Wada et. al. and Turner et. al. fails and should be withdrawn and all claims passed on to allowance.

Rejection under 35 USC §103(a) over Lew et. al. (US 5,599,583)

Claims 2-4, 10, 11, 14-15, 51, 52, 60, 61, 63-71 stand rejected under 35 USC §103(a) as being unpatentable over Lew et. al.

Lew et. al. is cited as disclosing the encapsulation of fungicides such as copper salts with water soluble polymers including PEG strengthened with polyvinylpyrrolidone wherein the active ingredient solids have a particle size of less than about 100 microns and the encapsulated materials a particle size of from 150 microns to 1500 microns. It is stated that the difference between the prior art and the claimed invention is that the former does not expressly disclose an inorganic antimicrobial encapsulated in a hydrophilic polymer having an average particles size of less than about 2000 microns. However, the Patent Office concludes that it would have been well within the skill of one of ordinary skill in the art and one would have been motivated to modify the prior art as above with the expectation that the encapsulation would render the copper salts easy to handle, reduce or eliminate exposure concerns, and provide a measure of control over the rate, timing and duration of the copper salt. The Examiner states that Applicants' arguments were considered but not persuasive. Specifically, the Examiner says that "[C]ontrary to Applicant's arguments there is no impermissible hindsight approach" and that "the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to sole a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by Applicant." In any event, the Examiner contends that there is nothing in the claims which indicates that the polymers swell but do not dissolve. Therefore, the Examiner concludes that the present

invention, as a whole, is prima facie obvious because every element of the invention has been collectively taught by the combined teachings of the references.

Applicants respectfully traverse the rejection and request reconsideration. Contrary to the Examiner's assertion that there is no "impermissible hindsight approach", impermissible hindsight is still very much alive and well (See MPEP 2141(II)(c). Regardless, in light of the foregoing amendments whereby Applicants have defined their antimicrobial agents as ion-exchange type antimicrobial agents comprising a ceramic carrier and ion-exchanged antimicrobial metal ions and specified that the amount of water absorbed by the hydrophilic polymer is sufficient to allow for ion transport within and through the hydrophilic polymer so as to facilitate the ion-exchange and subsequent release of an antimicrobially effective amount of the antimicrobial metal ions, neither of which concepts are disclosed in or obvious from Lew et. al., the claims as now presented are clearly patentable. Furthermore, Lew et. al., specifically requires and it is critical that the encapsulating polymer be water soluble so as to release or make available its encapsulated active ingredient (IA), i.e., the active ingredient becomes exposed and made available as the water soluble polymer dissolves away. Nothing; however, suggests that these water soluble polymers swell or absorb water so as to enable ion transport within and through the polymer. By analogy, the candy coating of a Tootsie Pop slowly dissolves away to expose the Tootsie Roll center, however, but for the candy at the interface between the consumer and the Tootsie Pop, the candy remains hard and unaffected by the saliva of the consumer. As noted above and as claimed, Applicants, on the other hand, require that their hydrophilic polymers absorb sufficient water to allow ion transport within and through the hydrophilic encapsulating material and specify that the release of their active ingredient, i.e., the antimicrobial metal ions, from within the hydrophilic polymer is as a result of this transport mechanism. In light of the foregoing, Applicants believe that any allegation of prima facie obviousness has been rendered moot and, in any event, is fully rebutted. Thus, the rejection should be withdrawn and the claims passed on to allowance.

Rejection under 35 USC §103(a) over Stapler et. al. (US 5,382,424)

Claims 1-4, 10, 11, 14-17, 60, 61 and 63-71 stand rejected under 35 USC §103(a) as being unpatentable over Stapler et. al. Stapler et. al. is cited as teaching the encapsulation of various antimicrobials, including quaternary ammonium salts and zinc and copper salts, in gelatin,

polyvinyl alcohol sucrose esters, and other similar materials wherein the shell thickness is on the order of 30 microns to 2 mm, preferably 70 to 110 microns, the overall particle diameter of the encapsulated antimicrobial is from about 2mm to about 9mm, preferably from about 3mm to about 7mm and the antimicrobial comprises from about 0.001% to about 2% of the total core contents. It is stated that the difference between the prior art and the claimed invention is that the prior art does not expressly disclose an inorganic antimicrobial which is encapsulated with a hydrophilic polymer having an average diameter of about 2000 microns. However, the Patent Office contends that the prior art amply suggests the same and that those skilled in that art would be motivated to modify the prior as above with the expectation that the encapsulation of a core containing the antimicrobial would allow control of breath odor without having to expectorate as with a mouthwash and that the combination of the ammonium compound and copper and/or zinc salt with the expectation that the combination would also have antimicrobial activity. The Examiner states that Applicants' prior arguments have been considered but are not deemed persuasive. Applicants respectfully traverse the rejection and request reconsideration.

The Examiner's characterization of Stapler et. al. is only partially correct, Stapler et. al. disclose a core-shell type breath protection microcapsule of from 2 mm to 9 mm in diameter comprising a shell formed of an ingestible material and a core comprising a liquid diluent and a breath control active/antimicrobial soluble in the diluent, wherein the breath control active/-antimicrobial agent may also be incorporated into the shell material. Nothing in Stapler et. al. would motivate one or suggest that one prepare an antimicrobial additive comprising a hydrophilic polymer and an ion-exchange type antimicrobial agent comprising a ceramic carrier and ion-exchanged antimicrobial metal ions having a particle size of from about 15μ to about 300μ, or, in the case of the encapsulation of the individual antimicrobial particles, about 300μ or less. Furthermore, like Lew et. al., nothing in Stapler et. al. suggests that its coatings are anything but water soluble coatings wherein only the polymer at the interface between the consumer and the microcapsule is affected by the saliva of the consumer. Indeed, Applicants' analogy to the Tootsie Pop is even more relevant here. In light of the foregoing and the claims as currently amended, Applicants believe that any allegation of prima facie obviousness has been rendered moot and, in any event, is fully rebutted. Thus, the rejection should be withdrawn and the claims passed on to allowance.

Conclusion

Contrary to the assertions of the Patent Office, nothing in the art motivates, supports or suggests i) the encapsulation of individual particles of an inorganic, ion-exchange type antimicrobial agent with a hydrophilic polymer, ii) the preparation of micro-sized particles comprising a hydrophilic polymer having dispersed therein a plurality of particles of an inorganic ion-exchange type antimicrobial agent, iii) the use of (i) or (ii) as an antimicrobial additive in a polymer composition, iv) that the compositions of (iii) have markedly and unexpectedly better performance and cost efficiency as compared to similar polymer compositions wherein the antimicrobial agent is not encapsulated with a hydrophilic polymer, etc. Clearly, in light of the foregoing arguments and amendments, any allegation of prima facie obviousness has been rendered moot, or in the alternative, has been fully rebutted. Applicants believe the claims as currently presented represent patentable subject matter and respectfully request that the rejections be withdrawn and the application passed on to allowance.

Claims Fees

By the foregoing amendments, Applicants have cancelled four dependent claims and added two dependent claims. Thus, no additional claims fees are necessary of due at this time.

Applicants believe all matters raised in the Office Action have been fully addressed. Should there be any questions, please contact the undersigned, Applicant's attorney.

Respectfully submitted,

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